



CLAIMS

Claims 1- 26 (cancelled).

Claim 27 (previously presented) A concentrated hormone pharmaceutical composition comprising: about 3.5 to about 80% of at least one hormone; and about 20 to about 96.5% of at least one solvent.

Claim 28 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, comprising:

about 10.1 to about 80% of said at least one hormone; and about 20 to about 89.9% of said at least one solvent.

Claim 29 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, comprising:

about 25.1 to about 80% of said at least one hormone; and
about 20 to about 74.9% of said at least one solvent.

Claim 30 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, further comprising a pharmaceutically acceptable carrier.

Claim 31 (previously presented) The concentrated hormone pharmaceutical composition according to claim 30, wherein the pharmaceutical composition is a suspension and wherein the pharmaceutically acceptable carrier is a viscous liquid.

Claim 32 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, wherein the pharmaceutical composition is selected from the group consisting of an ointment, a cream, a gel, a paste, a solution, a suspension and a lotion.

Claim 33 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, further comprising a coloring agent.

Claim 34 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, wherein said composition is in a powder form.

Claim 35 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, wherein said at least one hormone is selected from the group consisting of estrogen, testosterone and progesterone.

Claim 36 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, wherein said at least one hormone is selected from the group consisting of estradiol, estrone, estriol, testosterone, DHEA, pregnenolone, progesterone, and combinations thereof.

Claim 37 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, wherein the solvent is a mixture of ethoxy diglycol and propylene glycol.

Claim 38 (previously presented) The concentrated hormone pharmaceutical composition according to claim 37, wherein said mixture comprises 50% ethoxy diglycol and 50% propylene glycol.

Claim 39 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, wherein the solvent is selected from the group consisting of propylene glycol, ethoxy diglycol glycerin, mineral oil, fixed oil, emu oil, peanut oil, vitamin E oil, acetone, amylene hydrate, benzyl benzoate, corn oil, cottonseed oil, diethylene glycol monoethyl ether, ethyl acetate, isopropyl alcohol, methyl alcohol, methylene chloride, methyl isobutyl ketone,

polyethylene glycol 300, polyethylene glycol 400, polyethylene glycol 600, sesame oil, alcohol, a 50% ethoxy diglycol and 50% propylene glycol mixture, water, and combinations thereof.

Claim 40 (previously presented) A concentrated hormone pharmaceutical composition comprising: about 3.5 to about 100% of at least one hormone selected from the group consisting of estriol, estradiol, and combinations thereof; and about 0 to about 96.5% of at least one solvent.

Claim 41 (previously presented) The concentrated hormone pharmaceutical composition according to claim 40, comprising:

about 5.1% to about 100% of said at least one hormone selected from the group consisting of estriol, estradiol, and combinations thereof; and

about 0 to about 94.9% of said at least one solvent.

Claim 42 (previously presented) The concentrated hormone pharmaceutical composition according to claim 40, further comprising a pharmaceutically acceptable carrier.

Claim 43 (previously presented) The concentrated hormone pharmaceutical composition according to claim 40, wherein the pharmaceutical composition is selected from the group consisting of an ointment, a cream, a gel, a paste, a solution, a suspension and a lotion.

Claim 44 (previously presented) The concentrated hormone pharmaceutical composition according to claim 40, further comprising a coloring agent.

Claim 45 (previously presented) The concentrated hormone pharmaceutical composition according to claim 40, wherein said at least one hormone is a combination of estriol and estradiol.

Claim 46 (previously presented) The concentrated hormone pharmaceutical composition according to claim 45, wherein said at least one hormone is a combination of estriol and estradiol in a ratio of 5:5, 6; 4, 7:3, 8:2, or 9:1.

Claim 47 (previously presented) A concentrated hormone pharmaceutical composition comprising:

about 3.5 to about 100% of at least one hormone selected from the group consisting of estriol, estradiol, estrone, and combinations thereof; and

about 0 to 96.5% of at least one solvent.

Claim 48 (previously presented) The concentrated hormone pharmaceutical composition according to claim 47, comprising:

about 5.1 to about 100% of said at least one hormone selected from the group consisting of estriol, estradiol, estrone, and combinations thereof; and about 0 to about 94.9% of said at least one solvent.

Claim 49 (previously presented) The concentrated hormone pharmaceutical composition according to claim 47, further comprising a pharmaceutically acceptable carrier.

Claim 50 (previously presented) The concentrated hormone pharmaceutical composition according to claim 47, wherein the pharmaceutical composition is selected from the group consisting of an ointment, a cream, a gel, a paste, a solution, a suspension and a lotion.

Claim 51 (previously presented) The concentrated hormone pharmaceutical composition according to claim 50, further comprising a coloring agent.

Claim 52 (previously presented) The concentrated hormone pharmaceutical composition according to claim 47, wherein said at least one hormone is a combination of estriol, estradiol, and estrone.

Claim 53 (previously presented) The concentrated hormone pharmaceutical composition according to claim 52, wherein said at least one hormone is a combination of estriol, estradiol and estrone in a ratio of 5:4:1, 6:3:1, 7:2:1 or 8:1:1.

Claim 54 (previously presented) A concentrated hormone pharmaceutical composition comprising:
about 6.4 to about 80% of testosterone; and about 20 to about 93.6% of at least one solvent.

Claim 55 (previously presented) The concentrated hormone pharmaceutical composition according to claim 54 comprising:
about 10.1 to about 80% of said testosterone; and
about 20 to about 89.9% of said at least one solvent.

Claim 56 (previously presented) The concentrated hormone pharmaceutical composition according to claim 54, comprising:
about 25.1 to about 80% of said testosterone; and about 20 to about 74.9% of said at least one solvent.

Claim 57 (previously presented) The concentrated hormone pharmaceutical composition according to claim 54, further comprising a pharmaceutically acceptable carrier.

Claim 58 (previously presented) The concentrated hormone pharmaceutical composition according to claim 54, wherein the pharmaceutical composition is selected from the group consisting of an ointment, a cream, a gel, a paste, a capsule, a troche, a lozenge, a lollipop, a tablet, a tablet triturate, a sublingual tablet, a suspension and a lotion.

Claim 59 (previously presented) The concentrated hormone pharmaceutical composition according to claim 54, further comprising a coloring agent.

Claim 60 (previously presented) A concentrated hormone pharmaceutical composition comprising: about 10.1 to 90% of progesterone; and about 10 to about 89.9% of at least one solvent.

Claim 61 (previously presented) The concentrated hormone pharmaceutical composition according to claim 60, comprising:

about 20.1 to about 90% of said progesterone; and

about 10 to about 79.9% of said solvent.

Claim 62 (previously presented) The concentrated hormone pharmaceutical composition according to claim 60, further comprising a pharmaceutically acceptable carrier.

Claim 63 (previously presented) The concentrated hormone pharmaceutical composition according to claim 60, wherein the pharmaceutical composition is selected from the group consisting of an ointment, a cream, a gel, a paste, a capsule, a troche, a lozenge, a lollipop, a tablet, a tablet triturate, a sublingual tablet, a suspension and a lotion.

Claim 64 (previously presented) The concentrated hormone pharmaceutical composition according to claim 60, further comprising a coloring agent.

Claim 65 (previously presented) A method for producing a liquid or semi-solid concentrated hormone pharmaceutical composition comprising:

- (a) measuring at least one hormone and at least one solvent by using a balance in a clean room;
and
- (b) combining the ingredients of step (a) to form a composition by using an industrial scale mixer to ensure thorough mixing.

Claim 66 (previously presented) The method according to claim 65, further comprising:

- (c) running the mixture of step (b) through a large-scale ointment mill or homogenizer to decrease the particle size of the composition,

wherein the hormone is in a concentration of about 3.5 to about 80%.

Claim 67 (previously presented) The method according to claim 65, wherein the hormone is in a concentration of about 5.1 to about 80%.

Claim 68 (previously presented) The method according to claim 65 wherein the hormone is in a concentration of about 10.1 to about 80%.

Claim 69 (previously presented) The method according to claim 65, wherein the hormone is in a concentration of about 25.1 to about 80%.

Claim 70 (previously presented) The method for producing a liquid or semi-solid concentrated hormone pharmaceutical composition according to claim 65, wherein step (a) further comprises measuring at least one pharmaceutically acceptable carrier by using a balance.

Claim 71 (previously presented) The method according to claim 65, wherein the pharmaceutical composition is selected from the group consisting of an ointment, a cream, a gel, a paste, a suspension, a lotion and a solution.

Claim 72 (previously presented) The method for producing a liquid or semi-solid concentrated hormone pharmaceutical composition according to claim 65, further comprising:

(d) heating the composition to facilitate the formation of a solution.

Claim 73 (previously presented) The method for producing a liquid or semi-solid concentrated hormone pharmaceutical composition according to claim 65, further comprising a step of packing the concentrated hormone pharmaceutical composition in a container.

Claim 74 (previously presented) The method for producing a liquid or semi-solid concentrated hormone pharmaceutical composition according to claim 73, wherein the container is a graduated dispensing device selected from the group consisting of a metered dose tube, a metered dose pump, a metered dose syringe, a bottle, an ointment jar, a metered dose spray bottle, a bottle fitted with an adapter cap, a bottle, an ointment jar, a metered dose spray bottle, a bottle fitted with an adapter cap, a bottle with a pipette, a bottle with a burette, a jar with a metered dose scoop, a luer lock syringe, a pipette, a bottle top dispenser, a burette, and a metered dose scoop.

Claim 75 (previously presented) A kit for producing a liquid or semi-solid concentrated hormone pharmaceutical composition, comprising:

about 3.5 to about 80% of at least one hormone; and

about 20 to about 96.5% of at least one solvent,

wherein each element of the kit is provided in separated containers.

Claim 76 (previously presented) The kit according to claim 75, wherein said containers are graduated dispensing devices.

Claim 77 (previously presented) The kit for producing a liquid or semi-solid concentrated hormone pharmaceutical composition according to claim 75, comprising:

about 5.1 to about 80% of at least one hormone; and

about 20 to about 94.9% of at least one solvent.

Claim 78 (previously presented) The kit for producing a liquid or semi-solid concentrated hormone pharmaceutical composition according to claim 75, further comprising a pharmaceutically acceptable carrier.

Claim 79 (previously presented) The kit for producing a liquid or semi-solid concentrated hormone pharmaceutical composition according to claim 75, further comprising a container having internal divisions for separately packing the at least one hormone and the at least one solvent, wherein the at least one hormone and the at least solvent are combined by the purchaser to form the concentrated hormone pharmaceutical composition.

Claim 80 (previously presented) The kit according to claim 75, wherein the pharmaceutical composition is selected from the group consisting of an ointment, a cream, a gel, a paste, a suspension, a lotion, and a solution.

Claim 81 (currently amended) A The concentrated hormone pharmaceutical composition of claim 40, comprising:

~~about 3.5 to about 100% of at least one hormone selected from the group consisting of estriol, estradiol, and combinations thereof~~ 0% of at least one solvent; and

wherein the composition is in a powdered form.

Claim 82 (previously presented) The concentrated hormone pharmaceutical composition according to claim 81 further comprising a powdered base.

Claim 83 (previously presented) The concentrated hormone pharmaceutical composition according to claim 82 wherein said powdered base is selected from the group consisting of talc, lactose, and starch.

Claim 84 (previously presented) The concentrated hormone pharmaceutical composition according to claim 81, wherein the at least one hormone is a combination of estriol and estradiol.

Claim 85 (previously presented) The concentrated hormone pharmaceutical composition according to claim 81, wherein the at least one hormone is a combination of estriol and estradiol in ratio of 5:5, 6:4, 7:3, 8:2, or 9:1.

Claim 86 (currently amended) ~~A~~ The concentrated hormone pharmaceutical composition of claim 47, comprising:

~~about 3.5 to about 100% of at least one hormone selected from the group consisting of estriol, estradiol, estrone, and combinations thereof~~ 0% of at least one solvent; and

wherein the composition is in a powdered form.

Claim 87 (previously presented) The concentrated hormone pharmaceutical composition comprising:

about 6.1 to about 100% of at least one hormone selected from the group consisting of estriol, estradiol, estrone, and combinations thereof.

Claim 88 (previously presented) The concentrated hormone pharmaceutical composition according to claim 86, further comprising a powdered base.

Claim 89 (previously presented) The concentrated hormone pharmaceutical composition according to claim 88, wherein said powdered base is selected from the group consisting of talc, lactose, and starch.

Claim 90 (previously presented) The concentrated hormone pharmaceutical composition according to claim 86, wherein the at least one hormone is a combination of estriol, estradiol, and estrone.

Claim 91 (previously presented) The concentrated hormone pharmaceutical composition according to claim 86, wherein the at least one hormone is a combination of estriol and estradiol in ratio of 5:4:1, 6:3:1, 7:2:1 or 8:1:1.

Claim 92 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27, further comprising an anti-oxidant.

Claim 93 (previously presented) The concentrated hormone pharmaceutical composition according to claim 27 or claim 92, further comprising a preservative.

Claim 94 (previously presented) The concentrated hormone pharmaceutical composition according to any one of claims 27, 92 and 93, further comprising a chelating agent or synergist.

Claim 95 (previously presented) The concentrated hormone pharmaceutical composition according to any one of claims 27 and 92 to 94, further comprising an emulsifying agent.

Claim 96 (previously presented) The concentrated hormone pharmaceutical composition according to any one of claims 27 and 92 to 95, further comprising a suspending agent.

Claim 97 (previously presented) The concentrated hormone pharmaceutical composition according to any one of claims 27 and 92 to 96, further comprising a stiffening agent.

Claim 98 (previously presented) The concentrated hormone pharmaceutical composition according to any one of claims 27 and 92 to 97, further comprising an acidifying agent.

Claim 99 (previously presented) The concentrated hormone pharmaceutical composition according to any one of claims 27 and 92 to 98, further comprising an alkalizing agent.

Claim 100 (previously presented) The concentrated hormone pharmaceutical composition according any one of claims 27 and 92 to 99, further comprising a solubilizing agent.

Claim 101 (previously presented) The concentrated hormone pharmaceutical composition according to claim 33, wherein said coloring agent provides a distinct color profile for said composition.

Claim 102 (previously presented) The concentrated hormone pharmaceutical composition according to claim 44, wherein said coloring agent provides a distinct color profile for said composition.

Claim 103 (previously presented) The concentrated hormone pharmaceutical composition according to claim 102, wherein said coloring agent is red.

Claim 104 (previously presented) The concentrated hormone pharmaceutical composition according to claim 51, wherein said coloring agent provides a distinct color profile for said composition

Claim 105 (previously presented) The concentrated hormone pharmaceutical composition according to claim 104, wherein said coloring agent is red.

Claim 106 (previously presented) The concentrated hormone pharmaceutical composition according to claim 59, wherein said coloring agent provides a distinct color profile for said composition.

Claim 107 (previously presented) The concentrated hormone pharmaceutical composition according to claim 106, wherein said coloring agent is blue.

Claim 108 (previously presented) The concentrated hormone pharmaceutical composition according to claim 64, wherein said coloring agent provides a distinct color profile for said composition.

Claim 109 (previously presented) The concentrated hormone pharmaceutical composition according to claim 108, wherein said coloring agent is yellow.

Claim 110 (previously presented) A method of manufacturing a Bio-identical Hormone Replacement Therapy (BURT) product, said method comprising:

providing the concentrated hormone pharmaceutical composition as defined in any one of claims 27 to 29, and 32 to 39,

providing a pharmaceutically acceptable carrier,

combining the concentrated hormone pharmaceutical composition and the pharmaceutically acceptable carrier to produce a Bio-identical Hormone Replacement Therapy (BHRT) product having a desired concentration of said at least one hormone.

Claim 111 (previously presented) The method according to claim 110, wherein said pharmaceutically acceptable carrier is selected from the group consisting of a lotion base, an ointment base, a powder base, a cream base and a gel base.

Claim 112 (previously presented) A method of manufacturing a Bio-identical Hormone Replacement Therapy (BHRT) product, said method comprising:

providing the concentrated hormone pharmaceutical composition as defined in any one of claims 40, 41 and 43 to 46,

providing a pharmaceutically acceptable carrier,

combining the concentrated hormone pharmaceutical composition and the pharmaceutically acceptable carrier to produce a Bio-identical Hormone Replacement Therapy (BHRT) product having a desired concentration of said at least one hormone.

Claim 113 (previously presented) The method according to claim 112, wherein said pharmaceutically acceptable carrier is selected from the group consisting of a lotion base, an ointment base, a powder base, a cream base and a gel base.

Claim 114 (previously presented) A method of manufacturing a Bio-identical Hormone Replacement Therapy (BHRT) product, said method comprising:

providing the concentrated hormone pharmaceutical composition as defined in any one of claims 47, 48 and 50 to 53,

providing a pharmaceutically acceptable carrier,

combining the concentrated hormone pharmaceutical composition and the pharmaceutically acceptable carrier to produce a Bio-identical Hormone Replacement Therapy (BHRT) product having a desired concentration of said at least one hormone.

Claim 115 (previously presented) The method according to claim 114, wherein said pharmaceutically acceptable carrier is selected from the group consisting of a lotion base, an ointment base, a powder base, a cream base and a gel base.

Claim 116 (previously presented) A method of manufacturing a Bio-identical Hormone Replacement Therapy (BHRT) product, said method comprising:

- providing the concentrated hormone pharmaceutical composition as defined in any one of claims 54 to 56 and 58 to 59,
- providing a pharmaceutically acceptable carrier,
- combining the concentrated hormone pharmaceutical composition and the pharmaceutically acceptable carrier to produce a Bio-identical Hormone Replacement Therapy (BHRT) product having a desired concentration of said at least one hormone.

Claim 117 (previously presented) The method according to claim 116, wherein said pharmaceutically acceptable carrier is selected from the group consisting of a lotion base, an ointment base, a powder base, a cream base and a gel base.

Claim 118 (previously presented) A method of manufacturing a Bio-identical Hormone Replacement Therapy (BHRT) product, said method comprising:

- providing the concentrated hormone pharmaceutical composition as defined in any one of claims 60, 61 and 63 to 64,
- providing a pharmaceutically acceptable carrier,
- combining the concentrated hormone pharmaceutical composition and the pharmaceutically acceptable carrier to produce a Bio-identical Hormone Replacement Therapy (BHRT) product having a desired concentration of said at least one hormone.

Claim 119 (previously presented) The method according to claim 118, wherein said pharmaceutically acceptable carrier is selected from the group consisting of a lotion base, an ointment base, a powder base, a cream base and a gel base.

Claim 120 (previously presented) The method according to claim 65, wherein said step of measuring at least one hormone and at least one solvent is carried out using a balance in a clean room.

Claim 121 (previously presented) The method according to claim 65 or claim 120, wherein said step of combining the ingredients of step (a) to form a composition is carried out using an industrial scale mixer.

Claim 122 (previously presented) The method of any one of claims 65, 120 and 121, wherein said device is a large-scale ointment mill or a large-scale homogenizer.